



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,702	02/02/2004	Lev Korzinov	16491-022001	1300

20985 7590 10/26/2007
FISH & RICHARDSON, PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

BERTRAM, ERIC D

ART UNIT	PAPER NUMBER
----------	--------------

3766

MAIL DATE	DELIVERY MODE
-----------	---------------

10/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/770,702	Applicant(s) KORZINOV ET AL.	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/20/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-18, 26-39 and 41-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18, 26-39 and 41-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 8/20/07 have been fully considered but they are not persuasive. The Applicant argues that Zahorian's figures of merit do not reflect the merit of the information in the same signal; rather, they reflect the merit of the filtering applied to that signal. The Examiner respectfully disagrees. Despite the fact that different filtering techniques are utilized on the same signal, the filtering techniques do produce different information regarding the events of the cardiac biological signal. The signal that is output from each filter is still the same input signal, merely filtered differently, and thus possessing different extracted information. As described in Col. 8, lines 37-49, Zahorian then ranks the filtered cardiac biological signals based on the quality of the information describing the events, i.e., fetal heart beats. Even though the original cardiac biological signals contain all of the same information, the filtered cardiac biological signals inherently contain different information based on the type of filter applied. The 35 USC 102(b) rejections of claims 13, 14, 16-18, 26-38, 41-46 and 58 are still considered proper.

2. Applicant's arguments with respect to claims 13-15 and 37-39 (rejected under 35 USC 102(b) as being anticipated by Baker) and claims 13, 26-30, 33, 37, 41, 44 and 47-58 (rejected under 35 USC 102(b) as being anticipated by Anderson) have been considered but are moot in view of the new ground(s) of rejection, necessitated by applicant's amendment.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 13, 14, 16-18, 26-38, 41-46 and 58-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Zahorian et al. (US 5,524,631, hereinafter Zahorian). Zahorian discloses a method for determining a figure of merit for cardiac biological signals. Zahorian describes receiving a plurality of cardiac biological signals 2 from a patient using sensor 1, which includes information describing the heart beat and heart rate of the patient (Col. 4, lines 49-67). These signals are then processed to produce a plurality of heart rate estimates, and a figure of merit is determined for each estimate, wherein the figure of merit is based on the quality of the information, specifically continuity constraints and a measure of periodicity (Col. 8, lines 25-40). These figures of merit are then compared to each other and ranked to determine which has the highest ranking, and then the heart rate associated with that figure of merit is handled for medical purposes, while the rest are discarded (see figure 3 and Col. 8, lines 41-49). Specifically, the selected heart rate corresponding to the highest figure of merit is sent to a remote display or through a modem (Col. 9, lines 30-40).
5. Regarding claim 27, each event (i.e., fetal heart beat) must be identified in order to find an accurate fetal heart rate.

6. Regarding claims 35, 36, 45 and 46, this sent heart rate is considered an “episode” that inherently summarizes the relevance of the information since only the most relevant (i.e., highest figure of merit) will be sent to the display.

7. Regarding claims 17, 18, 30, 31 and 41-43, Zahorian discloses that the estimates are taken over, and associated with, a period of approximately 0.5 seconds (Col. 8, lines 47-48). Furthermore, Zahorian describes determining which signal is the most meritorious by comparing and ranking the signals. Therefore, the signal with the highest figure of merit is placed in a determined to be in the “most meritorious” category.

8. Regarding claim 28, if the heart rate is found to be zero, this would inherently be identified as an asystole event.

9. Regarding claim 29, Zahorian discloses that the events are identified by based on a range of normal fetal heart rates (Col. 8, lines 33-36).

10. Regarding claims 33 and 44, Zahorian discloses a graph with a time stamped x-axis that displays the time with the most-meritorious events used to create the signal (see figure 8 and Col. 9, lines 40-47).

11. Regarding claim 58, the information in the biological signal describes the current heart rate state of the fetal heart.

12. Regarding claims 59 and 60, the category of the events (that being that each event is a fetal heart beat) has already been pre-determined by Zahorian.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3766

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 13-15 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, JR. et al. (US 2002/0137994 A1, hereinafter Baker) in view of Zahorian. Baker discloses a method for determining the merit of cardiac biological signals to determine their quality. Baker describes receiving a plurality of cardiac biological signals describing events (par. [0035-0036]). A weight is assigned to the plurality of signals that is based on a plurality of variables, including signal-to-noise ratio

Art Unit: 3766

and arrhythmia probability (higher probability = more severe condition) (see claim 15 and par. 0178). Based on these weights, certain events are used to determine a pulse rate, while some events may be rejected if they do not meet certain criteria (See abstract). However, Baker does not disclose transmitting meritorious information to a remote medical receiver.

17. Attention is directed to the secondary reference of Zahorian, which, as described above, discloses a method for determining the merit of information in a cardiac signal. Furthermore, Zahorian discloses sending the meritorious information to a remote medical receiver in order to save the information in fixed disk storage (Col. 9, lines 30-40). Therefore, it would have been obvious to one of ordinary skill in the art to modify Baker by sending the meritorious information to a remote medical receiver in order to save the information for the benefit of allowing future access to and/or review of the information.

18. Claims 13, 26-30, 33, 37, 41, 44 and 47-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 4,336,810, hereinafter Anderson) in view of Zahorian. Anderson discloses a system and method for handling information received from the body. An ECG signal is received that contains information describing arrhythmic events of the heart (Col. 5, lines 56-68). The raw signal is recorded and time stamped so that the time of the event is documented (Col. 8, lines 59-65). The events are compared to known templates to determine the severity of the cardiac condition, i.e., whether or not a known arrhythmia is present (Col. 7, lines 3-9). If the information matches a template, then the event is handled for classification and an arrhythmia

Art Unit: 3766

counter is updated (Col. 7, lines 17-21). If the information does not match a template, the information is discarded, or set aside, so that it may be given independent consideration (Col. 7, lines 10-13). However, Anderson does not disclose transmitting meritorious information to a remote medical receiver.

19. Attention is directed to the secondary reference of Zahorian, which, as described above, discloses a method for determining the merit of information in a cardiac signal. Furthermore, Zahorian discloses sending the meritorious information to a remote medical receiver in order to save the information in fixed disk storage (Col. 9, lines 30-40). Therefore, it would have been obvious to one of ordinary skill in the art to modify Anderson by sending the meritorious information to a remote medical receiver in order to save the information for the benefit of allowing future access to and/or review of the information.

20. Regarding claims 27, 28, 49-51, and 54-56, Anderson discloses that the abnormalities that can be identified include tachycardia, bradycardia, and dropped beats (i.e., flutter) (Col. 8, lines 1-5).

21. Regarding claims 48 and 53, Anderson discloses that the ECG data can be analyzed by breaking the signal into different parts by time length (Col. 7, lines 60-65).

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3766

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

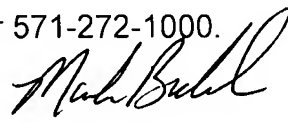
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3766

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766



Mark Bockelman
Primary Examiner
Art Unit 3766

EDB